

JUN - 4 2003

K023691

510(k) Summary

(Pursuant To Section 12 of the SAFE MEDICAL DEVICES ACT of 1990)

General Provisions

Submitter's Name and Address	Boston Scientific Corporation 2525 Walsh Avenue Santa Clara, California 95051-1316
Contact Person	Timothy J. Johnson Director of Regulatory Affairs (408) 970-7343
Classification Name	Device, Coronary Saphenous Vein Bypass Graft, Temporary, For Embolization Protection
Common or Usual Name	Embolic Protection Guidewire
Proprietary Name	Boston Scientific FilterWire EX™ Embolic Protection System
Manufacturing Facilities	Boston Scientific Corporation 2525 Walsh Avenue Santa Clara, California 95051-1316

Name of Predicate Device

Medtronic® AVE PercuSurge GuardWire
Plus® Temporary Occlusion and Aspiration
System (K003992, K014223)

Device Description

The Boston Scientific FilterWire EX™ Embolic Protection System is a temporary intra-vascular 0.014" guidewire filtration system that is placed distal to the vessel lesion to be treated by interventional procedures. The system consists of a protection wire in 190 and 300 cm lengths, an EX Delivery Sheath, an EX Soft Tip Retrieval Sheath and accessories. A separately packaged EX Bent Tip Retrieval Sheath will also be available as an alternate tool for retrieving the FilterWire protection wire. When deployed, the protection wire's filter bag is designed to capture and recover emboli that may be produced during the angioplasty/stenting procedure while allowing blood flow to continue. Once deployed, the protection wire is used as a standard 0.014" steerable guidewire.

The EX Delivery Sheath has a radiopaque marker at the tip for visualization of the system under fluoroscopic imaging. The tip of the protection wire and the filter loop are radiopaque. At the completion of the procedure, the filter is resheathed and then removed from the patient using one of two available retrieval sheaths. The 190 cm wire is compatible with the Boston Scientific Trooper Patriot™ Extension Wire for over-the-wire catheter exchanges.

Intended Use

The FilterWire EX Embolic Protection System is indicated for use as a guidewire and embolic protection system in containing and removing embolic material (thrombus/ debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.5 to 5.5 mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.

Summary of Technological Characteristics

The FilterWire EX Embolic Protection System incorporates a filter membrane on a Nitinol loop located approximately six (6) cm proximal to the 0.014 inch diameter guidewire's distal tip. The guidewire (protection wire) is sheathed in a 1.3 mm outer diameter EX Delivery Sheath (an easy exchange sheath). The sheath extends distal to the protection wire's nosecone (just distal to the filter loop/filter assembly). The sheathed FilterWire protection wire, with its radiopaque floppy guidewire tip exposed, is advanced through a guiding catheter (0.065 inch minimum inner diameter) to the saphenous vein graft of choice and across the intended lesion as would a normal coronary guidewire. The protection wire and its floppy tip can be rotated independently of the EX Delivery Sheath because the FilterWire filter loop assembly is mounted on a spinner tube and the guidewire can rotate under the filter assembly as needed. Once across the target lesion, the loop is deployed by slightly withdrawing the EX Delivery Sheath. The Nitinol loop expands to circumferentially appose the vessel wall. A platinum alloy coil is wound around the Nitinol filter loop to allow fluoroscopic visibility. If the filter loop placement is unsatisfactory, the filter loop can be resheathed and repositioned. If the filter loop placement in the vessel is satisfactory, the EX Delivery Sheath can be completely withdrawn. Once the filter loop expands, blood flows through the polyurethane filter membrane. The filter membrane utilizes laser drilled holes each measuring approximately 110 microns in diameter, to allow blood to flow through while capturing embolic material.

While the FilterWire is deployed, the stenting and/or angioplasty catheters are threaded over the 0.014" guidewire. During the intervention, the blood flow is monitored angiographically. After the interventional treatment, an EX Soft Tip or Bent Tip Retrieval Sheath is used to cross the treatment site and stents, if deployed, and to retrieve the FilterWire. Advancement of the retrieval sheath over the filter loop causes the filter bag to close, retaining embolic material in the

filter bag. The assembly is then removed through the vessel and into the guiding catheter.

The device is similar to the predicate device in that it is an interventional means to provide embolic protection for angioplasty/stenting treatments to saphenous vein graft lesions and it provides that embolic protection distal to the target lesion. Both systems are based on 0.014 inch diameter guidewire platforms. The primary difference in technologies involve a filter based technology versus a balloon occlusion method with aspiration.

Non-Clinical and Clinical Test Summary

In-vitro testing consisted of dimensional testing, tensile/torque testing and functional testing. Biocompatibility, packaging testing, product shelf life testing and functional testing in animal models have also been successfully conducted. Test results verified that the FilterWire EX Embolic Protection System met all applicable product specifications and is deemed adequate for its intended use.

Clinical evaluation was conducted in a randomized clinical trial involving a total of 864 saphenous vein graft subjects. The FilterWire EX Embolic Protection System was evaluated in a trial cohort of 110 patients versus a 103 patient control population with no embolic protection provided. Thirty (30) day rates of major adverse cardiac events (MACE) including death, myocardial infarction, emergent coronary artery bypass grafting or repeat target vessel revascularization demonstrated a 7.3% rate for the FilterWire EX versus a 7.8% rate for no protection (not significant).

A second trial cohort consisting of 332 patients (FilterWire EX) and 319 patients (commercially available Medtronic® AVE PercuSurge GuardWire Plus® Temporary Occlusion and Aspiration System) demonstrated 30 day MACE rates of 9.9% (FilterWire EX) and 11.6% (GuardWire Plus). It was concluded that the cumulative 30-day MACE rate for the FilterWire EX Embolic Protection System (9.9%) compared to the cumulative 30-day MACE rate for the Medtronic® AVE PercuSurge GuardWire Plus® Temporary Occlusion and Aspiration System (11.6%) was significantly equivalent when tested to a delta of 5.5% ($p = 0.0016$). The upper 95% confidence interval of the difference between the two groups was 3.1% (95% C.I., -6.4%, 3.1%).

Boston Scientific Corporation considers the FilterWire EX Embolic Protection System substantially equivalent to the embolic protection guidewire legally marketed by Medtronic AVE based on a comparison of intended use and the results of *in-vitro* testing, *in-vivo* testing and clinical evaluation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2003

Mr. Timothy J. Johnson
Director of Regulatory Affairs
Boston Scientific Corporation/EPI
2525 Walsh Avenue
Santa Clara, CA 95051-1316

Re: K023691
Trade/Device Name: FilterWire EX™ Embolic Protection System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: NFA
Dated: May 29, 2003
Received: May 29, 2003

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

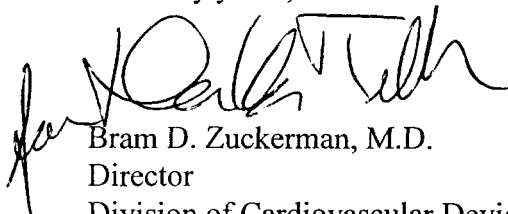
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over the typed name.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number – K023691

Device Name: FilterWire EX™ Embolic Protection System


Indications for Use:

The FilterWire EX Embolic Protection System is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/ debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.5 to 5.5 mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE
IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-the-Counter Use _____
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K023691